



L0001785

May 17, 2017

Document Processing Desk 6(a)(2)  
Office of Pesticide Programs (7504P)  
U. S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**RE: 6(a)(2) Study Report Submission – Ethofumesate Technical (EPA Registration #264-611) – Ecotoxicology Study Reports**

Dear Sir/Madam,

Bayer is submitting new information to EPA related to Ethofumesate Technical (EPA Registration # 264-611) as required by conditions set forth in 40 CFR § 159.165(b)(2). This information is not necessarily a new adverse effect of the subject chemical, but is rather new information submitted for EPA's own review and evaluation because the data meet EPA's administrative reporting criteria.

The Study Reports and the findings are as follows:

1. Pseudokirchneriella Subcapitata Growth Inhibition Test With Ethofumesate-NC8493 (AE C508493) – MRID # 50279401. The following green algae study, performed with a metabolite of ethofumesate, was performed according to OECD guideline 201. Overall, the 72 hour EC<sub>50</sub> indicates that the metabolite is less active than the parent ethofumesate; however, the NOEC level is noted to be lower. Due to a statistically detected inhibition of growth rate at >1 mg metabolite/L, the NOEC was defined as 0.367 mg metabolite/L. In reporting these findings, no impact is expected to the risk assessment.
2. Zebra Fish (Danio Rerio), Life Cycle Test, Flow Through Conditions – Ethofumesate – MRID # 50279402. This study was conducted according to OECD guideline 215. Overall a fish population is not likely to be adversely effected by the following effects. The most sensitive parameter was growth of parental adult fish, with slight effects defining a NOEC of 0.156 mg a.i./L. However, lack of a dose response relationship was observed, expect for the highest test level of 2.5 mg a.i./L. No effects were observed on reproduction or sex ratios.

This information is being submitted to the EPA pursuant to EPA's interpretation of requirements imposed on registrants by Section 6(a)(2) of FIFRA.

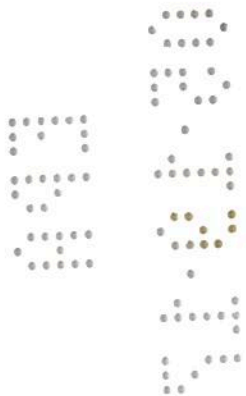
The content of this 6(a)(2) study report is also related to the Ethofumesate Technical Registration Review DCI (ID # GDCI-110601-1697). Therefore, please share it with Jordan Page, Chemical Review Manager.

Should EPA have questions, please feel free to contact me at any time.

Sincerely,



Sundee Williams  
AE Compliance Manager  
Crop Science  
A Division Of Bayer  
North American Knowledge & Information Management  
(919)549-2255  
CC:  
Ann Hanger, CA Department of Pesticide Regulation  
Jeanine Broughel, NY Department of Environmental Conservation





**TRANSMITTAL DOCUMENT**

**264-611 Ethofumesate Technical**

**CP-6(a)(2)-OPPTS-USA-D-015730**

**Transmittal Date**

May 18, 2017

*Sundee K. Williams*

Company Official:

Company Name:

Bayer CropScience LP

Company Contact:

Williams, Sundee

Company Telephone:

(919) 549-2255

Bayer CropScience LP  
2 T.W. Alexander Drive  
Research Triangle Park  
NC 27709 Durham  
United States of America

DOCUMENTUM



## **BIBLIOGRAPHY OF SUBMITTED DATA**

<b>Study No.</b>	<b>Study</b>	<b>Guideline No.</b>	<b>EPA MRID No.</b>
<b>RPT Study Reports</b>			
<b>Series 850 Ecological Effects Test Guidelines</b>			
<b>Group D Terrestrial &amp; Aquatic Plants, Cyanobacteria, &amp; Terrestrial Soil Core Microcosm Test Guidelines</b>			
<b>1</b>	Bruns, E.: Pseudokirchneriella subcapitata growth inhibition test with ethofumesate-NC8493 (AE C508493); Bayer CropScience AG, Monheim, Germany; Report No.: EBADL032; Document No.: M-436372-01-2; 2012-08-03; Pages: 72	850.4500	50279401
<b>SUPP Supplemental</b>			
<b>2</b>	Teigeler, M.: Zebra fish (Danio rerio), life cycle test, flow through conditions - Ethofumesate; Fraunhofer Institut, Schmallenberg, Germany; Report No.: BAY-035/4-60/A; Document No.: M-464613-02-2; 2013-12-12; Pages: 318	850.SUPP	50279402



May 17, 2017

Jordan Page  
Chemical Review Manager  
U.S. Environmental Protection Agency  
Pesticide Re-evaluation Division (7508P)  
One Potomac Yard (South Building)  
2777 South Crystal Drive  
Arlington, VA 22202-4501

**RE: Notification Of DCI (ID # GDCI-110601-1697) Related 6(a)(2) Study Report  
Submission – Ethofumesate Technical (EPA Registration #264-611) – Ecotoxicology Study  
Reports**

Dear Sir/Madam,

Bayer is submitting new information to EPA related to Ethofumesate Technical (EPA Registration #264-611) pursuant to EPA's interpretation of requirements imposed on registrants by Section 6(a)(2) of FIFRA.

The study reports are entitled:

1. Pseudokirchneriella Subcapitata Growth Inhibition Test With Ethofumesate-NC8493 (AE C508493) – MRID # 50279401.
2. Zebra Fish (*Danio Rerio*), Life Cycle Test, Flow Through Conditions – Ethofumesate – MRID # 50279402.

Because these are also relevant to the Ethofumesate Technical Registration Review DCI (ID # GDCI-110601-1697), the 6(a)(2) Document Processing Desk has been asked to share a copy of this 6(a)(2) study report with you.

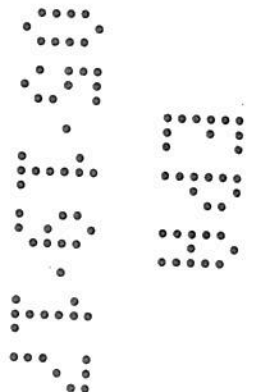
The 6(a)(2) submission Cover Letter is attached for your reference. Should EPA have questions, please feel free to contact me at any time.

Sincerely,

Sundee Williams  
AE Compliance Manager  
Crop Science  
A Division Of Bayer  
North American Knowledge & Information Management  
(919)549-2255

CC:  
Ann Hanger, CA Department of Pesticide Regulation  
Jeanine Broughel, NY Department of Environmental Conservation

Crop Science  
A Division Of Bayer  
2 T. W. Alexander Drive  
Research Triangle Park, NC 27709







# Receipt for Section 3



S: 1003787

Milestone Email: [sundee.williams@bayer.com](mailto:sundee.williams@bayer.com)

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: 6A2 Data

Fee For Service: ☐ Yes ☒ No

Company: 264 BAYER CROPSCIENCE LP

V

Billable: ☐ Yes ☒ No

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 24

Product #: 264-611 Product Name: ETHOFUMESATE TECHNICAL

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 17-May-2017



OPP Rec'd Date: 18-May-2017



Front End Date: 18-May-2017



Risk Manager Send Date: 18-May-2017



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Portal submission pkg# 19752. 6a2 data.

Receipt Content

Des

Study

View/Edit

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

DOCUMENTUM